

REMARKS

Applicant respectfully requests reconsideration. Claims 1, 2, 5-8, 11, 16, 17, 19-22, 24-27 and 29 were previously pending in this application. By this amendment, Applicant is canceling claims 19-22, 24-27 and 29 without prejudice or disclaimer. New claims 30-33 have been added. Support for the newly added claims can be found throughout the instant specification, for example, on pages 4 and 15. As a result, claims 1, 2, 5-8, 11, 16, 17 and 30-33 are pending for examination with claim 1 being an independent claim.

No new matter has been added.

Interview with Examiners

Applicant respectfully thanks Examiners Paras and Montanari for conducting an interview with Applicant's assignee's representative. During the interview, the outstanding rejections and potential claim amendments were discussed, although no final agreement was reached.

Rejections under 35 U.S.C. §112

The Examiner has rejected claim 19 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Without conceding the correctness of this rejection, and in the interest of expediting prosecution of the instant application, Applicant has canceled claim 19. Accordingly, this rejection is believed to be moot and its withdrawal is respectfully requested.

The Examiner has rejected claims 1, 2, 5-7, 11, 16, 17, 19-22, 24-26 and 29 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner has argued that at issue is the question of what is a natural promoter. The Examiner argues that it is the "nature" of a promoter to start transcription and that the use of "naturally", therefore, in the context of the claim language would not be understood by the ordinary artisan.

Applicant respectfully traverses. Applicant maintains that the Examiner has not met the burden to sustain this rejection. The Examiner bases the rejection on a meaning that is unreasonable and inconsistent with the plain language of the claims and teachings of the instant specification and that he himself concedes to be counterintuitive. A counterintuitive meaning, which by definition one of ordinary skill in the art would not ascribe to the rejected terminology, is not sufficient to demonstrate that one of ordinary skill in the art would not discern a meaning for the rejected terminology such that the rejected claims remain insolubly ambiguous.

MPEP §2173.02 sets forth the standard for determining definiteness. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. Page 2100-218, column 2.

Applicant maintains that those skilled in the art would understand what is claimed when the claims are read in light of the instant specification. In the “Background of the Invention” section of the instant application, examples of promoters from one gene that have been used to control transcription of the coding sequence from another are provided. The instant application then provides that milk protein promoters can also be used in the expression of proteins. The rejected terminology is then exemplified in the instant specification in a manner consistent with a milk protein promoter being from one gene and a coding sequence from another (See, e.g., pages 3, line 24, to page 4, line 2, where the promoter can be one “naturally associated with any protein which is normally secreted into mammalian milk”; page 6, lines 22-23, where if the protein is normally secreted, the signal sequence can be “that which is naturally associated with the desired protein”.) Two working examples are also provided that further exemplify the relationship of the promoter to the expressed gene. These examples describe the expression in mouse mammary gland of hepatitis B surface antigen and tissue plasminogen activator, each of which are in nature unrelated to the milk protein promoter used. Based on the teachings of the instant specification, which include the clear and consistent use of the rejected terminology, Applicant maintains that the metes and bounds of the rejected claims would be clear to those of ordinary skill in the art. One of ordinary skill in the art would understand that the claims refer to genes expressed by

mammalian milk protein promoters, which promoters the genes are not associated with as found in nature (i.e., genes heterologous to the mammalian milk protein promoters.) Thus, the claim language possesses more than the “reasonable degree of particularity and distinctness” required. MPEP §2173.02 at page 210—218, columns 1 and 2. With the benefit of hindsight, other language might be made clear and precise, but that is not the test. *Id.*

To further support the above arguments, Applicant submits herewith a Declaration of Harry M. Meade. The Meade Declaration discusses (A) the content of the application (e.g., paragraphs 7, 8, 10-12 and 14) (B) the teachings of the prior art (e.g., paragraphs 6 and 10); and (C) how one of ordinary skill in the art would have interpreted “not naturally control transcription” on April 9, 1986 (e.g., paragraphs 11-13). The Meade Declaration makes clear that the application was the first to teach producing medically relevant proteins using an animal’s existing milk production system to express a desired gene (e.g., paragraphs 14 and 15). The Meade Declaration makes clear that “not naturally control transcription” would have been understood by one of ordinary skill in the art to exclude milk protein promoters that controlled transcription of a gene in the absence of genetic engineering (e.g., paragraphs 11-13). Therefore, the Meade Declaration demonstrates that one of ordinary skill in the art would not reasonably interpret the milk protein promoter of the claims to be one that does not by nature want to control transcription, as the Examiner has suggested, and that it would be understood by an ordinarily skilled artisan that a promoter which does not naturally control transcription of a gene is one that would not control transcription of the gene in the absence of genetic engineering.

Accordingly, it is respectfully requested that this rejection be withdrawn.

Rejection Under 35 U.S.C. §102

The Examiner has rejected claims 1, 2, 5-7, 11, 16, 17, 19-22 and 24-26 under 35 U.S.C. § 102(b) as allegedly being anticipated by Qsaba et al.

Applicant respectfully traverses. In light of the above interpretation of the language of the rejected claims and, it follows, their scope, Qsaba et al. cannot be interpreted to provide Applicant’s claimed constructs. Qsaba et al. merely provide a nucleotide sequence of the rat alpha-lactalbumin gene and identifies its putative promoter. Such a teaching does not provide a construct that includes a mammalian milk protein promoter sequence and a gene not naturally

under the transcriptional control of such promoter. In fact, the Examiner has still not demonstrated that any construct that includes the identified rat alpha-lactalbumin promoter is even provided. Nevertheless, even if, *arguendo*, a construct was provided, the construct would be one that includes a gene and a promoter that does naturally control its transcription. Such a construct is not within the scope of Applicant's claims.

For the record, Applicant notes that a construct, while it may be a circular piece of DNA, is not necessarily so and may be, for example, linear.

As discussed above, the Examiner bases this rejection on his interpretation of "naturally". In the interest of compact prosecution and in simplifying issues for a potential appeal, if the Examiner does not withdraw this rejection, Applicant requests that the Examiner indicate whether this rejection would be overcome were the term "naturally" given the construction Applicant suggests. See MPEP §2173.06 at page 2100-233 (This "approach is recommended from an examination standpoint because it avoids piecemeal examination in the event that the Examiner's 35 U.S.C. §112, second paragraph rejection [is not affirmed]").)

Reconsideration and withdrawal of this rejection is respectfully requested.

Double Patenting Rejection

The Examiner has rejected claims 1, 2, 5-8, 11, 16, 17, 19-22, 24-27 and 29 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-5 of U.S. Patent No. 6,727,405.

Without conceding the correctness of the rejection, and in the interest of expediting prosecution, Applicant anticipates filing a terminal disclaimer to obviate this rejection. See MPEP §804.02 at page 800-32, column 1 (A terminal disclaimer "is not an admission of the propriety of the rejection".)

Interview Request

Applicant has been actively prosecuting this divisional application for over fifteen years. It appears that the only remaining obstacles to allowance turn on the definition of the claim term "naturally". If the Examiner would prefer some alternative claim term to define Applicant's pioneering invention, Applicant invites him to contact the undersigned to suggest it, as

encouraged by numerous MPEP provisions. See, e.g., MPEP §707.07(j) at page 700-130, column 1; Form Paragraph 7.43.02 Allowable Subject Matter, Claims Rejected Under 35 U.S.C. §112, Second Paragraph; MPEP §2173 at page 2100-218, column 2, and page 2100-219, columns 1 and 2.

In addition, if the Examiner would like further views of Declarant Harry Meade, Ph.D., a pioneer in the field, regarding the field in 1986, he is encouraged to contact the undersigned to arrange a possible interview.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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